

- Group I: claims 1-10, drawn to a method of maintaining a desired shape of corneal tissue comprising administering to a patient a stabilizing agent;
- Group II: claims 11-16, drawn to a composition comprising fibril associated collagens and small leucine-rich repeat proteoglycans (SLRPs);
- Group III: claims 17-21 and 22-24, drawn to a method of maintaining corneal curvature comprising applying a composition to a cornea to stabilize corneal curvature by reacting the said composition with collagen fibril and building linkages among corneal fibrils, and a method of making the composition thereof; and
- Group IV: claims 25-26, drawn to a method of correcting a patient's corneal curvature comprising insert orthokeratological lens into a patient's eye and applying a stabilizing agent to the eye thereof.

Office action, page 2. Applicants are required to elect a group for examination on the merits. *Id.* In response, Applicants elect **Group I** (claims 1-10), with traverse. Further to their election of Group I, Applicants are also required to elect a single disclosed composition comprising (i) one molecule of fibril associated collagen with interrupted triple-helices (FACIT) from claim 6, and (ii) one molecule of small leucine-rich repeat proteoglycans (SLRP) from claim 7. Applicants elect **Type VI collagen** as the single fibril associated collagen with interrupted triple-helices (FACIT) and **decorin** as the single small leucine-rich proteoglycans (SLRP).

In traversing the restriction requirement, Applicants note that the Examiner is restricting Applicants' Markush groups in claims 6 and 7. The criteria for restriction of Markush-type claims is set forth in M.P.E.P. § 803.02, which states:

If the members of the Markush group are sufficiently few in number, or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not require restriction.

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. See, M.P.E.P. § 803. Thus, the Examiner should not restrict Applicants' invention unless examination of the claims results in a serious burden.

In the present case, the Examiner has not shown that there would be a serious burden to examine at least some of the alleged inventions together in a single application, in particular, the members of the claimed Markush group. For example, the Office has not suggested that there is an unreasonable number of members in the claimed Markush group. There are, in fact, only 4 FACITs recited and only 7 SLRPs recited. All FACITs share a common structure (collagens with interrupted triple-helices), as do all SLRPs (small leucine-rich repeat proteoglycans). In view of the structural relatedness of the members of each Markush group, a search for one member would necessarily provide much information with respect to the remaining members. Accordingly, there is no undue search burden for the Office.

Additionally, Applicants respectfully submit that they have a statutory right under 35 U.S.C. § 112, second paragraph, to claim the subject matter they regard as their invention as they choose. Issuing a restriction requirement within a claim forces Applicants to carve up that claim and pursue the non-elected subject matter in separate applications, thereby violating Applicants' right under section 112. Indeed, the C.C.P.A. has characterized such action as tantamount to a refusal to examine. See *In re Weber*, 198 U.S.P.Q. 328 (C.C.P.A. 1978); *In re Haas*, 198 U.S.P.Q. 334 (C.C.P.A. 1978).

In *Weber*, the court warned against the consequences of requiring an applicant to divide up the subject matter presented in a single claim, stating:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

Weber, 198 U.S.P.Q., at 331.

The Examiner has provided no substantive reason to justify the violation of Applicants' statutory right under 35 U.S.C. § 112, second paragraph, to claim the subject matter they regard as their invention as they choose.

Accordingly, Applicants respectfully request that the Examiner reconsider the present grouping of claims and rejoin those groups that do not pose an undue burden on the Examiner, including those recited in the Markush groups of claims 6 and 7.

If necessary, please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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